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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 10-12 March 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation application for **Rheumocam** (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Ltd, concerning the addition of a new strength and a new pharmaceutical form for horses.

The Committee adopted by consensus positive opinions for the following type II variation applications:

BROADLINE regarding new indications;

DRAXXIN regarding a change in the withdrawal period;

Nobilis IB4-91 (subject to a worksharing procedure with nationally authorised product) regarding efficacy changes; and

Versican Plus DHPPi, Versican Plus DHPPi/L4R and Versican Plus DHPPi/L4 (subject to a worksharing procedure) regarding efficacy changes.

More information about the above mentioned medicines, including their full indication, will be published on the Agency's website.

MUMS/limited market

Following the Committee's review of two requests for classification under the MUMS/limited market policy, the CVMP classified:

- An immunological product for cattle as indicated for MUMS/limited market but was not eligible for financial incentives as an alternative product already exists for the indication; and
- An antibacterial product for horses as indicated for MUMS/limited market but was not eligible for financial incentives as an alternative product already exists for the indication.

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Pharmacovigilance

The Committee reviewed the PSURs for **Procox**, **Recuvyra** and **Veraflox** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **Cimalgex**, **Eurican Herpes 205** and **NexGard** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats (EMEA/CVMP/EWP/005/2000-Rev.3) for a 6-month period of public consultation. The guideline has been amended to include requirements for generic products for topical administration, statistical evaluation, assessment of systemically acting ectoparasiticides and clarification on certain aspects of the SPC and other product information.

Environmental Risk Assessment

The Committee adopted a draft reflection paper on poorly extractable and/or non-radiolabelled substances (EMA/CVMP/ERA/349254/2014) for a 6-month period of public consultation. This reflection paper presents a pragmatic approach on how to deal with substances which are difficult to extract from soil. The paper proposes a number of options to applicants on how to perform OECD TG 307 studies when the extraction efficiency (recovery) of the substance in soil is lower than the minimum required for validating the test results.

Pharmacovigilance

The Committee adopted a reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014). This reflection paper has been developed to provide an overview of the different tools used by national competent authorities and the European Medicines Agency to date to promote pharmacovigilance reporting. In addition, further activities that may be beneficial in increasing pharmacovigilance reporting in general and particularly with regard to food producing animals have been examined.

The documents above will be published on the Agency's website.

Working parties and expert groups

Further to the establishment of a new Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) in December 2014 for the purpose of providing advice and developing guidance to industry on therapies that are entirely new to the veterinary domain (novel therapies), CVMP agreed on priority topics for which guidance will be developed by ADVENT in the first instance.

The priorities chosen relate to specific aspects relating to the development of:

- products containing stem cells;
- products containing monoclonal antibodies;
- tumour vaccines intended for use in animals (yet to be confirmed).

Initially guidance will be developed in the form of Questions and Answers, which may be updated taking into account additional aspects as needed. The public, in particular industry and other stakeholders, are invited and encouraged on a continuous basis to submit their views to the European

Medicines Agency concerning relevant novel therapies and related products for which they consider guidance would be useful. Such contributions would be anonymised and processed for consideration by CVMP and ADVENT. Contributions should be sent to ADVENT@ema.europa.eu using a template linked to the work plan.

The Committee endorsed the work plan for 2015 for the CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT).

The work plan will be published on the Agency's website.

International harmonisation

The Committee adopted two VICH guidelines, following the sign-off by the VICH Steering Committee:

- VICH GL53: Guideline on electronic exchange of documents: electronic file formats, for implementation;
- VICH GL54: Guideline on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for release for public consultation in the EU at step 4 of the VICH process.

The guidelines will be published on the Agency's website.

Notes

1. 'MUMS' stands for minor use minor species.
2. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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